DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

SEP 22 1997

Mr. Mitsuru Takiura
23501 Madero
Mission Viejo, CA 92691-2764

Dear Mr. Takiura:

0012 '97 SEP 19 P1:24

This is in response to your letter of April 2, 1997 making a submission to the Food and Drug Administration (FDA) pursuant to section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the act). Your submission states that you are making the following statement in the labeling of the product "Probiata":

> Replenishes healthy intestinal flora, avoiding disorders such as diarrhea, constipation and yeast discomfort caused by antibiotic usage.

This claim does not come within the coverage of section 403(r)(6) of the act. We would point out that section 403(r)(6) of the act makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statement that you are making for "Probiata" suggests that this product is intended for at least one of these purposes, in that it claims to be effective in "avoiding disorders such as diarrhea, constipation and yeast discomfort caused by antibiotic usage." Therefore, this claim does not meet the requirements of section 403(r)(6) of the act. This claim suggests that this product is intended for other than food use within the meaning of section 201(g) of the act and that it is subject to regulation under the drug provisions of the act.

If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

973-0163

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Please contact us if we may be of further assistance.

Sincerely yours,

James Tanner

James Tanner, Ph.D.
Acting Director,
Division of Programs and
Enforcement Policy
Office of Special Nutritionals
Center for Food Safety
and Applied Nutrition

Copies:
FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300
FDA, Los Angeles District Office, Office of Compliance, HFR-PA200
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of Enforcement, HFC-200

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VIA FEDERAL EXPRESS
TEL: 202.401.9636

Office of Special Nutritionals (HFS-455)
Center for Food Safety and Applied Nutrition
FOOD AND DRUG ADMINISTRATION
200 "C" Street, S.W.
Washington, D.C. 20204

Dear Sir or Madam:

Pursuant to Section 6 of the Dietary Supplement Health and Education Act of 1994, 21 U.S.C. § 343(r)(6), this is to notify FDA that our company has begun to include in the labeling of its **PROBIATA™** Dietary Supplement which contains *Lactobacillus acidophilus*, the following statements of nutritional support: "Replenishes healthy intestinal flora, avoiding disorders such as diarrhea, constipation and yeast discomfort caused by antibiotic usage."

Sincerely,

Mitsuru Takiura
President

MT/mat

23501 Madero, Mission Viejo, California 92691-2764 (714) 855-2776 • FAX: (714) 458-2764